

URGENT FIELD SAFETY NOTICE

**Arjo Minstrel floor lift
Field Action FSN-POZ-004-2018**

<Customer Name>

<Customer Address>>

Cc: Chairman Medical Board and relevant Head of Departments

Date: <DD-MMM-YYYY>

Product Issue: Risk of spreader bar detachment from lift **WITHOUT** a scale

Affected Product: 1263 units manufactured solely since Jan 2008 until March 2010

Resolution: Spreader bar replacement for a new revision of the part (free of charge)

Affected Serial No.: **SERIAL NUMBER RANGE: from** [REDACTED] **to** [REDACTED]

Field Correction Notice: FSN-POZ-004-2018

Pages: 2

Dear Customer

Our records indicate that you bought one or more Minstrel passive floor lifts with a serial number listed as above.

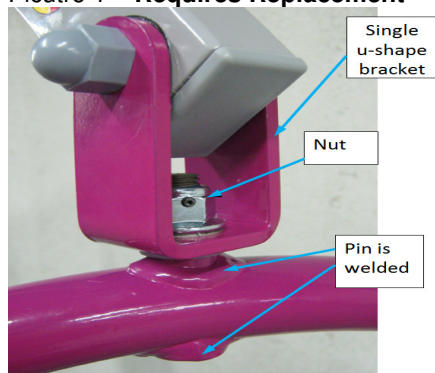
This letter is to inform you of a corrective action that will be performed to prevent risk of the spreader bar detachment from the lifting arm during patient transfer.

The issue we found can cause potential risk of the patient falling and injuries as a consequence. We have received a small number of incidents from the market claiming the spreader bar detachment when the device was being used. From our investigation which includes our evaluation of worst-case scenarios it was concluded that there is a remote chance that the problem may occur.

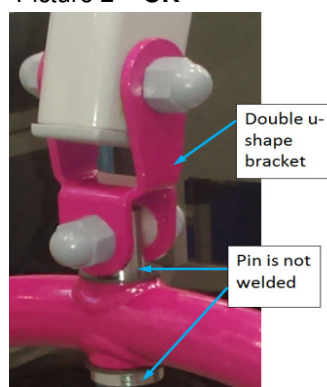
Please note that all Minstrel passive lifts currently manufactured (outside of the above serial numbers) are free of this issue.

We would like to ask you kindly to verify the version of the spreader bar your lifts are equipped with following below pictures:

Picture 1 – Requires Replacement



Picture 2 – OK



If your spreader bar in **requires replacement** (picture 1), take the device out of usage immediately and contact Arjo Sales and Service (following contact information in the customer response form).

If your spreader bar is **OK (picture 2)**, please return the customer response form to the address indicated in this attachment with a note that no replacement is required. The device can be used without any risk.

This action is to replace the spreader bar with its equivalent having improved design preventing risk of the detachment. The replacement will be performed free of charge.

Next Steps

1. Please make sure that all caregivers and users of the Minstrel referenced on the previous page are made aware of this Field Notice and all listed devices at your facility are available to be reworked during Arjo service technician visit.
2. Complete and sign the enclosed Customer Response Form and return this form to the local Arjo office.
Note: An Arjo Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to replace your device, free of charge.

Transmission of this Field Notice

This Arjo Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

This field safety notice has been reported to the National Competent Authorities in your country.

Additional Comment

<If applicable, write any additional comments you want to forward to a customer>.

Customer Response Form

FSN-POZ-004-2018

Reference: Urgent Field Safety Notice, Arjo Minstrel passive floor lift.

Our records indicate that the Minstrel device shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

ArjoHuntleigh ORDER NO.	ITEM NO.	SERIAL NO.	MANUFACTURING DATE
<X>	<1>	<XXXX>	<Date>
<Y>	<2>	<YYYY>	<Date>

Record the total number of affected device currently located at your facility here please → ____.

Please check the appropriate boxes below:

- We have read the Minstrel Field Safety Notice and we understand the communication and the required actions.
If checked : please provide information where the affected devices are physically located.

Field Safety Notice Receipt and Customer Response Form Completion and Certification

Current Facility Name			
Contact Name / Title			
Address (no PO boxes, please)			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

- We have sold/moved our Minstrel floor lift to another facility.
If checked : please provide new facility information below.

New Facility Name			
Contact Name / Title			
Address*			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

IF YOUR SPREADER BAR IS OK:

- We hereby confirm that we have verified the spreader bar version following the pictures on the page 1 and the spreader bar is ok – free of the design error.

Name:	
Signature	



PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

Arjo South East Asia Pte. Ltd.
31 Kaki Bukit Road 3
#05-06/07 Techlink Lobby B
Singapore 417818

CONTACT

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